

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

APPLICANT : Stefan WILLMANN et al  
SERIAL NO. : 10/598,416  
CUSTOMER NO. : 27384  
FILED : August 29, 2006  
FOR : IMPROVED METHOD FOR THE TIME DOSAGE OF  
MEDICAMENTS  
ART UNIT : To Be Assigned  
EXAMINER : To Be Assigned

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February 23, 2007

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

SIR:

Pursuant to 37 CFR §§ 1.56, 1.97 and 1.98, Applicants respectfully request that the Examiner consider the references listed on the attached Form PTO/SB/08.

**I. Timeliness, Fees and Certifications in lieu of Fees**

This information disclosure statement is being filed within three months of the filing date of the application, or within three months of entry into the national stage, or before the mailing of a first Office Action on the merits. Pursuant to 37 CFR § 1.97(b), consideration of this information disclosure statement does not require a fee or a statement under 37 CFR § 1.97(e). However, should the Assistant Commissioner determine that a fee is, in fact, due, the Assistant Commissioner is hereby authorized to charge the fee to Deposit Account No. 14-1263.

**II. Copies of Listed References**

Copies of all references listed on the attached Form PTO/SB/08 are being supplied. Copies of U.S. patents are not included pursuant to Pre-OG Notice dated July 11, 2003.

### **III. Concise Statement of Relevance**

All references listed on the attached Form PTO/SB/08 are referred to in the specification which indicates the degree of relevance.

The Examiner will note that English language counterparts or Abstracts of non-English language references are also enclosed, as follows:

**DE 101 60 270 – Cited on pages 1 and 5 of the specification. Corresponds to US2005119832. Abstract provided.**

**DE 103 45 836 – Cited on pages 1 and 5 of the specification. Corresponds to US2005075274. Abstract provided.**

**DE 103 45 837 – Cited on page 1 of the specification. Corresponds to US2005074803. Abstract provided.**

Consideration of the foregoing in relation to this application is respectfully requested.

Respectfully submitted,

NORRIS McLAUGHLIN & MARCUS, P.A.

By /Kurt G. Briscoe/  
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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> ( Not for submission under 37 CFR 1.99)	<b>Application Number</b>		10598416	
	<b>Filing Date</b>		2006-06-29	
	<b>First Named Inventor</b>	Stefan WILLMANN et al		
	<b>Art Unit</b>			
	<b>Examiner Name</b>			
<b>Attorney Docket Number</b>		100717-691 KGB		

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	1	101 60 270	DE		2003-06-26	BAYER AG		<input type="checkbox"/>
	2	103 45 836	DE		2005-04-21	BAYER TECHNOLOGY SERVICES		<input type="checkbox"/>
	3	103 45 837	DE		2005-04-21	BAYER TECHNOLOGY SERVICES		<input type="checkbox"/>

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
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Application Number	10598416
Filing Date	2006-08-29
First Named Inventor	Stefan WILLMANN et al
Art Unit	
Examiner Name	
Attorney Docket Number	100717-691 KGB

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**NON-PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>5</sup>
	1	Product Information - "Diprifusor™- Target Controlled Infusion (TCI) in anaesthetic practice"; AstraZeneca Anaesthesia, New Edition (1999), Alderley House, Alderley Park, UK	<input checked="" type="checkbox"/>
	2	WILLMANN, Stefan et al; "PK-Sim®: a physiologically based pharmacokinetic 'whole-body' model"; Biosilico Vol. I, No 4, (September 2003) pages 121-124, Elsevier Science Ltd.	<input checked="" type="checkbox"/>
	3	PRICE, Paul S.; "Modeling interindividual variation in physiological factors used in PBPK models of humans"; Critical Reviews in Toxicology, 33(5); pages 469-503 (2003) Taylor and Francis, Inc.	<input checked="" type="checkbox"/>
	4	OHNISHI, A.; "A review of clinical use of theophylline in acute asthma: factors influencing kinetic disposition and drug interactions"; Methods Find Exp. Clin Pharmacol 22(4); pages 253-258, (2000) Prous Science	<input checked="" type="checkbox"/>
	5	MITENKO, Paul A, et al; "Pharmacokinetics of intravenous theophylline"; Clinical Pharmacology Therapeutics; 14, (1973) pages 509-513, Montreal, Quebec, Canada	<input checked="" type="checkbox"/>
	6	JAMESON, John P., et al; "Theophylline Pharmacokinetics in black Zimbabwean males"; Therapeutic Drug Monitoring, 12, pages 54-58 (1990) Raven Press, Ltd. New York	<input checked="" type="checkbox"/>
	7	GAL, Peter et al; "Theophylline disposition in obesity"; Clin. Pharmacol. Ther (April 1978), Vol. 23, No. 4, The C.V. Mosby Co., pages 438-444	<input checked="" type="checkbox"/>
	8	JACKSON, S.H.D., et al; "The relationship between theophylline clearance and age in adult life". Eur. J. Clin Pharmacol, Springer-Verlag (1989) 36: pages 29-34	<input checked="" type="checkbox"/>
	9	KATA, Z et al; "Developmental changes of unbound theophylline"; Department of Pediatrics, Gifu University School of Medicine, 40 Tsukasa, Gifu 500 Japan	<input checked="" type="checkbox"/>

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Application Number	10598416
Filing Date	2006-08-29
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Art Unit	
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Attorney Docket Number	100717-691 KGB

10	VALENTI, S.; "Bioavailability and pharmacokinetics of a new controlled-release theophylline preparation in the form of capsules containing Pellets"; Respiration 52; (1967) pages 195-200	<input checked="" type="checkbox"/>
11	MULLER et al; "Theophylline kinetics in peripheral tissues in vivo in humans"; Naunyn-Schmiedeberg's Arch Pharmacol (1995) 352; pages 438-441	<input checked="" type="checkbox"/>
12	MEYER, Marvin c.; "Bioequivalence of immediate-release theophylline capsules"; Biopharmaceutics & Drug Disposition (1999) 20; pages 417-419	<input checked="" type="checkbox"/>

If you wish to add additional non-patent literature document citation information please click the Add button

**EXAMINER SIGNATURE**

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> See Kind Codes of USPTO Patent Documents at [www.USPTO.GOV](http://www.USPTO.GOV) or MPEP 901.04. <sup>2</sup> Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>3</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>4</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>5</sup> Applicant is to place a check mark here if English language translation is attached.

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Attorney Docket Number	100717-691 KGB

**CERTIFICATION STATEMENT**

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

**OR**

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

- ☒ See attached certification statement.
- ☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.
- ☐ None

**SIGNATURE**

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Kurt G. Briscoe/	Date (YYYY-MM-DD)	2006-02-23
Name/Print	KURT G. BRISCOE	Registration Number	33141

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

## Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

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3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
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5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.